

REMARKS

Status Summary

Claims 1-33 are pending in the present application. Claims 1-33 presently stand rejected. Claims 34-36 were previously cancelled. With this amendment, claim 1 has been amended and new claims 37 and 38 have been added. Reconsideration of the application is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1-4, 11, 15, 19-21, 24 and 30 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,029,659 to O'Connor (hereinafter "O'Connor"). These rejections are respectfully traversed.

Independent claim 1 of the present application recites a holder for holding a dispensing container system which is adapted to dispense a quantity of a fluid contained therein on movement thereof relative to the holder and further includes a dispensing counter means for counting the number of quantities of the fluid dispensed. Independent claim 1 recites that the holder has a moulded plastics body with inner and outer surfaces. The inner surface bounds a cavity adapted to receive the dispensing container system in movable relation thereto. Independent claim 1 as amended recites that the holder has a moulded counter advance means within the cavity configured to co-operate with the dispensing counter means during use on relative movement between the dispensing container system and the body to advance the dispensing counter means to indicate the dispensing of a quantity of the fluid. Independent claim

1 also recites that the body is formed with an outlet port in communication with the cavity such that the fluid dispensed from the dispensing container system is dischargeable therethrough. Independent claim 1 further recites that an aperture extends through the body from the outer surface to the inner surface in alignment with the counter advance means.

Applicants respectfully submit that O'Connor does not anticipate independent claim 1 or the claims that depend therefrom as O'Connor does not disclose all the features of independent claim 1. In particular and without limitation, O'Connor does not disclose a holder having a moulded counter advance means within a cavity of the holder configured to co-operate with a dispensing counter means during use on relative movement between a dispensing container system and a body of the holder to advance the dispensing counter means to indicate the dispensing of a quantity of the fluid.

O'Connor discloses an inhalation device in the nature of a metered dose inhaler with a counter. The device is designed to work with existing respiratory drugs. The device is comprised of an L-shaped medication dispenser in which a counter is attached. A downward force applied to the top portion of the canister protruding from the top of the L-shaped medication dispenser releases a single dose of the aerosol medication and increments the counter. The device contains a visual display of the current count and thus an indication of the metered doses remaining in the aerosol canister. The counter can be electronic, mechanical or electro-mechanical in nature. Counting devices for other shaped dispensers such as cylindrical dispensers are also

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described. Other options such as a warning alarm, automatic power conservation shutdown of the display, and full computer monitoring functions are also disclosed.

Figure 5 of O'Connor provides a side plan view of the counter **40** fastened to L-shaped metered dose delivery device **10**. The counter **40** is fastened to L-shaped delivery device **10** by being inserted into opening **60** in L-shaped delivery device **10**. Push button momentary switch **50** is depressed into counter **40** and thus increments the count. Figure 5 also illustrates how a downward pressure applied to the top **20** of the metered dose aerosol canister **11**, forces the hollow stem **21** back into the canister **11**, and at the same time forces push button **50** to contact and increment counter **40**, by being depressed and pushed into counter **40**. When hollow stem **21** has moved sufficiently into canister **11** to open an internal valve, a metered dose of the aerosol medication is released under pressure through the hollow stem **21** and out through opening **22**. The aerosol medication continues to travel out through opening **12** of the delivery device **10**, where it can be inhaled by the patient. Visual display **41** displays the current count.

Thus, it is quite clear that O'Connor discloses a push button **50** that is integral to the dose counter **40** and is depressible to activate the dose counter **40**. As recited in claim 1 of the present application, the holder forms the moulded counter advance means that resides within the cavity of the holder. The moulded counter advance means advances the dispensing counter means to indicate the dispensing of a quantity of the fluid. The moulded counter advance means is an integral part of the holder,

however, not the dispensing counter means. O'Connor does not disclose a moulded counter advance means that is part of the holder. Rather, O'Connor discloses a push button that is integral to the dose counter.

For the reasons outlined above, applicants respectfully submit that O'Connor fails to disclose each and every feature recited by claim 1. Claims 2-4, 11, 15, 19-21, 24 and 30 depend from claim 1. As such, applicants respectfully submit that the rejection of claims 1-4, 11, 15, 19-21, 24 and 30 under 35 U.S.C. §102(b) should be withdrawn and the claims allowed at this time.

Claim Rejections – 35 U.S.C. § 103

Claims 5-10, 12-14, 16-18, 23, 25-29, 31 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over O'Connor in view of International Patent Publication No. WO 98/56444 to Rand et al. (hereinafter, "Rand"). These rejections are respectfully traversed.

Claims 5-10, 12-14, 16-18, 23, 25-29, 31 and 32 depend from claim 1. Claim 1 is not rendered obvious by O'Connor, alone or in combination with other references. For example, O'Connor teaches away from a holder having a moulded counter advance means within a cavity of the holder configured to co-operate with a dispensing counter means during use on relative movement between a dispensing container system and a body of the holder to advance the dispensing counter means to indicate the dispensing of a quantity of the fluid. Further, to modify O'Connor in such a manner would change the principles of operation of the delivery device of O'Connor.

O'Connor does not disclose a moulded counter advance means that is part of the holder. Instead, O'Connor discloses a push button that is integral with the dose counter and is movable up and down within the dose counter to advance the counter. In O'Connor, the dose counter **40** is placed in the delivery device **10** with the integral push button **50** extending upward from the dose counter **40** in proximity to and under the canister **11** near the stem **21**. The dose counter **40** is rigidly held in place in opening **60** of the back wall of the delivery device **10**. During operation, the dose counter **40** does not move with the depression of canister **11** in O'Connor. Upon depression, the canister **11** contacts the movable push button **50** of the dose counter **40** and pushes the push button **50** downward to cause the dose counter **40** to count the dosage.

The delivery device as disclosed in O'Connor holds the dose counter stationary within its walls thereby requiring the push button that is integral to the dose counter to be movable relative to the delivery device and the dose counter to count each dosage. Such a requirement teaches away from a holder for holding a dispensing container system having a moulded counter advance means within a cavity of the holder configured to co-operate with the dispensing counter means. In the holder as recited in claim 1 of the present application, the moulded counter advance means does not move relative to the holder since it is moulded as part of the holder. Thus, the moulded counter advance means does not move as required by the delivery device in O'Connor.

Further, to modify the delivery device of O'Connor to include a holder having a moulded counter advance means within a cavity of the holder configured to co-operate with the dispensing counter means as recited in claim 1 of the present application would

change the principles of operation of the delivery device. To have the features recited in claim 1 of the present application, the delivery device of O'Connor would have to be totally redesigned to remove the push button from the dose counter and to change the manner in which the dose counter is held within the delivery device, so that the element that replaces the push button would be stationary and the dose counter would be permitted to move within the delivery device. Such a change would destroy the principles of operation of the delivery device disclosed in O'Connor. Therefore, the teachings of O'Connor, alone or in combination with other references, are not sufficient to render claim 1 or the claims that depend therefrom *prima facie* obvious. (See MPEP § 2143.01)

Rand fails to overcome the significant shortcomings of O'Connor. A combination of O'Connor with Rand would create a proposed modification of the delivery device of O'Connor that would change the principle of operation of such a delivery device as described above. Therefore, claim 1 and the claims that depend therefrom are not rendered obvious by O'Connor. To find otherwise could only be based on hindsight of the claimed invention, which is not permitted in the test for obviousness.

Accordingly, since claims 5-10, 12-14, 16-18, 23, 25-29, 31 and 32 depend from claim 1, applicants respectfully submit that these claims are not rendered obvious by the cited references. Therefore, applicants respectfully submit that the rejection of claims 5-10, 12-14, 16-18, 23, 25-29, 31 and 32 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

New Claims

New claims 37 and 38 have been added by this amendment as indicated above. Independent claim 37 recites a method of moulding a holder of a dispensing container system. Claim 38, which depends from claim 37, recites similar features as the holder recited in claim 1 of the present application. For the same reasons as described above, claims 37 and 38 are not anticipated or rendered obvious by O'Connor and/or Rand, either alone or in combination. For example, neither O'Connor nor Rand disclose, teach or suggest all the steps recited in either claim 37 or claim 38. No new matter has been added.

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CONCLUSION

In light of the above remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

FEE DUE

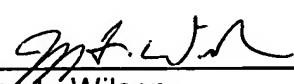
A check in the amount of \$1,050.00 is enclosed for the fee due. The Commissioner is authorized to charge any deficiencies of payment associated with the filing of this correspondence to Deposit Account No. 50-0426 to avoid the unintentional abandonment of the instant application.

Respectfully submitted,

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